Support for the amendments to claims 2 and 3 can be found, for example, on pages 13 and 14. The amendment to Claim 5 incorporates Claim 6; the amendment to Claim 15 incorporates Claim 16; and the amendment to Claim 48 incorporates Claim 49. Therefore basis for these amendments can be found at least in the claims as originally filed.

Entry of these amendments, based on claims currently pending in the application prior to issuance of the office action finally rejecting the claims, is proper since the amendments narrow the scope of the claims and reduce issues on appeal, should the application not be determined to be allowable.

Election/Restrictions

Application indicates that claims 1-20, 23-34, 36, 37, and 39-49 are pending, but only provides the status of claims 1-9, 15, 16, and 39-49. Although the discussion on pages 2-4 indicates that the claims have been restricted into eight groups, page 4 also makes clear that all claims are being treated as joined through linking claims 1-4, 10, 11, 13, 15-17, and 21-23. Accordingly, should these claims be determined to be allowable, all claims will be examined to the extent they read on nucleic acids as the substance to be detected.

Should the examiner not agree with this understanding, it is requested the undersigned be advised immediately so that a petition for supervisory review may be filed.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1-9, 15-16, and 39-49 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claim 1, directed to determining the susceptibility of a human patient to prostate cancer by determining whether a sample of nucleic acid and/or protein from prostate cells contains Pax2 nucleic acid or protein, has been cancelled.

Claims 2-9, 15-16 and 39-49 are directed to a method of diagnosing and assessing prostate cancer and are fully enabled. Indeed, the examiner acknowledges on page 6, lines 9-13 of the Office Action, that the application is enabling for a diagnostic method comprising the steps of (i) obtaining a sample of the tissue, containing mRNA, in which prostate cancer is suspected or in which prostate cancer may be or has been found, and (ii) detecting the presence or absence of mRNA expression which is associated with prostate cancer.

Claim 5 has been amended to specify that the nucleic acid is mRNA. This is fully enabled by the specification.

Claims 15 and 48 have been amended to recite a method of diagnosis wherein the sample is a sample of urine, semen, blood or lymph fluid containing cells from the prostate tissue. The amendment clearly identifies the samples for use in the method. It is intended that the reference in the independent claims will encompass cells in tissue or in fluid samples, not just those obtained by biopsy.

Although the examiner alleges that there is no experimental evidence in the application to show that prostate cells are found in urine, semen, blood or lymph fluid, it is clear from pages 11 and 12 of the application that prostate cells can be found in these fluids. Furthermore, at the priority date of the application it was common knowledge to those skilled in the art that prostate cells could be found and enriched from these fluids to provide suitable samples for analysis.

This is evidenced by the enclosed article abstracts. Brandt *et al.* (1996, Cancer Res. 56:4556-4561) teaches that prostate cancer cells can be detected in human peripheral blood and discloses a technique for the isolation of cells from this type of sample; Gardiner *et al.* (1996, Br. J. Urol. 78:414-8) teaches that prostate cells can be detected in ejaculate specimens; and Iwakiri *et al.* (1993, J. Urol. 149:783-6) teaches that prostate cells can be detected in urine and indicates one way in which samples can be obtained.

Applicants disagree that one of ordinary skill in the art would be unable to perform the aspects of the invention in the absence of explicit guidance in the application. The application clearly teaches that the level of detectable Pax2 mRNA can be used to diagnose patients with prostate cancer and to differentiate between benign and metastatic forms of the disease.

Whether the disclosure is enabling is a legal conclusion based upon several underlying factual inquiries. See *In re Wands*, 858 F.2d 731, 735, 736-737, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir.1988). As set forth in *Wands*, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. In light of the above amendments, the state of the prior art, the relative skill of those in the art and the guidance provided by the specification, it is clear that one of skill could make and use the claimed invention without undue experimentation.

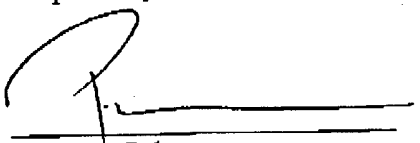
Claims 2-9, 15-16, and 39-49 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claims 2 and 3 have been amended to recite that the methods involve "detecting the presence or absence of mRNA expression which is associated with prostate cancer". The objected to language, "Comparing the amount of any Pax 2 mRNA detected in the test sample with the amount of any Pax 2 mRNA detected in a control sample known to contain non-cancerous or non-metastatic cells", has been deleted. In addition, Claims 2 and 3 have been amended to recite diagnosing the presence of prostate cancer in light of the result obtained in step (ii). This additional step makes it clear that the level of Pax2 mRNA is used directly to diagnose the presence of prostate cancer.

Claims 40 and 42, directed to the methods of claims 2 and 3, respectively, wherein the amount of detectable Pax 2 mRNA is at least 1.5 fold higher than the amount of detectable Pax 2 mRNA in the sample of non-cancerous or non-metastatic cells, have been cancelled.

Allowance of claims 2-5, 7-9, 15, 39, 41, and 43-48, as amended, is respectfully solicited.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

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PABST PATENT GROUP LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, Georgia 30361
(404) 879-2151
(404) 879-2160 (Facsimile)